



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,223	03/02/2004	Mel H. Epstein	3474.1001-011	3953
21005 7590 11/19/2007 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER KWON, BRIAN YONG S	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 11/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/791,223

Applicant(s)

EPSTEIN ET AL.

Examiner

Brian S. Kwon

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 19, 26-27, 30-33 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 20-25, 28, 29 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03/02/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/21/07</u> .                                                | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1614

## **DETAILED ACTION**

### ***Applicants Response to Restriction Requirement Acknowledged***

1. Applicant's election with traverse the Group II along with amphetamine (alone) and Alzheimer's disease as the elected species is acknowledged. Claims 18, 20-25, 28-29 and 34 read on the elected species.

Accordingly, claims 1-17, 19, 26-27, 30-33 and 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims.

### ***Information Disclosure Statement***

2. Acknowledgement is made of applicant's submitting of the information disclosure statement (IDS) on 09/21/07. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement (IDS) has been considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18, 20-25 and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 28 and 29 recite "optionally, a methamphetamine, wherein at least about 85 mole percent of the total amphetamine and methamphetamine content of the composition is l-amphetamine" and "optionally, a methamphetamine, wherein at least about 95 mole percent of the total amphetamine and methamphetamine content of the

Art Unit: 1614

composition is l-amphetamine” respectively. When a methamphetamine is “optionally” not selected, the instant invention is reasonably construed that the claimed composition which is intended to administer for the treatment of Alzheimer’s diseases is prepared without the presence of methamphetamine. However, the phrases following “wherein” clause, “at least about 85 moles percent of the total amphetamine and methamphetamine content...” and “at least about 95 moles percent of the total amphetamine and methamphetamine content...”, require the presence of methamphetamine in said composition at all times. This inconsistency in the claims leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

For the examination purpose, the terms are construed as meaning “the amphetamine is at least about 95 mole percent l-amphetamine relative to the total amphetamine content of the composition” similar to claim 34.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1614

4. Claims 18, 20-25, 28-29 and 34 are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 4, 17, 21 and 23 of copending Application No. 11/305495. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because one having ordinary skill in the art would have known that the methamphetamine (l-methamphetamine) would be metabolized to amphetamine (l-amphetamine) in human body and would provide similar activity as the instantly claimed l-amphetamine in the treatment Alzheimer's disease. See Specification, page 20, lines 12-14 of the copending 11/305495 and Gilles et al., The Journal of Pharmacology and Experimental Therapeutics, Vol. 292, No. 3, pp. 1042-1047, 2000.

5. Claims 18, 20-25, 28-29 and 34 are rejected under the judicially created doctrine of double patenting over claims 1-23, 28-35 of U. S. Patent No. USP 7244769 and claims 1-28 of U.S. Patent No. 6828351.

Although the patented claims do not specifically identify the use of said l-amphetamine in the treatment of Alzheimer's disease, one having ordinary skill in the art, reading the entire specification (see for example USP'351, column 9, line 4-5, column 10, line 61, column 14, lines 57-58, column 19, lines 4-5, column 28, lines 58-59, column 48, line 10 and USP'769, column 12, line 27, column 14, lines 36-37, column 17, line 56, column 23, lines 65-66, column 29, lines 50-51, column 40, line 29, column 63, line 34), would have expected that l-amphetamine is useful for the treatment of Alzheimer's disease by improving in memory consolidation. Thus, using the specification as

“dictionary” in this ODP (obviousness-type double patenting) rejection analysis, the patented claims of US’769 and US’351 make obvious the instant invention.

### Conclusion

6. No Claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

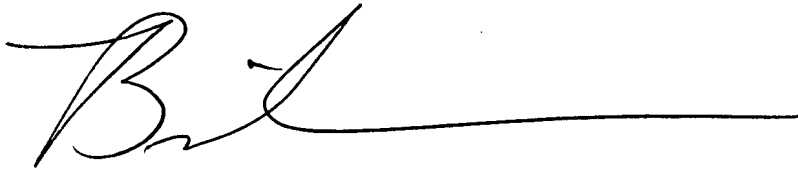
Brian Kwon

Application/Control Number: 10/791,223

Page 6

Art Unit: 1614

**Primary Patent Examiner**  
**AU 1614**

A handwritten signature in black ink, consisting of a stylized 'B' followed by a long horizontal line.